

# Notice of Allowability

Application No.

09/647,503

Examiner

Tatyana Zalukaeva

Applicant(s)

TREMONT, SAMUEL J.

Art Unit

1713

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 04/28/2004.
2. ☒ The allowed claim(s) is/are 15-20.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

## **EXAMINER'S COMMENT/REASONS FOR ALLOWANCE**

### ***Terminal Disclaimer***

1. The terminal disclaimer filed on 04/28/2004 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 6,471,955 has been reviewed and is accepted. The terminal disclaimer has been recorded.

### ***Allowable Claims***

2. Claims 15-20 are allowed over the prior art of record.

### ***Reasons for Allowance***

3. The following is an examiner's statement of reasons for allowance: Drug delivery system comprising crosslinked polymer, active ingredient and specific linker are well known in the art. Thus Tremont (U.S. 5,827,925) discloses a drug delivery system adapted to release an effective amount of a drug at pH values of about 1 to 7 without releasing a significant amount of the drug at pH values of about 7 and above, the system comprising a polymeric material and a drug covalently bonded to the polymeric material (abstract). Suitable active ingredients which can be used in the practice of the invention herein include compounds which contain an hydroxyl ( $--OH$ ) group, a carboxylic acid group ( $--COOH$ ), an amino group ( $--NH_2$  or an  $--NHR$  group wherein R is an alkyl group of 1-4 carbons), a thiol group ( $--SH$ ), or an enolizable carbonyl group (i.e., aldehydes, ketones and amides) (col.3, lines 14-20). Polymeric

Art Unit: 1713

materials which themselves cannot form such a covalent bond can be modified by attaching a linker group to such polymer. The linker group can be any suitable compound which can bond to both the polymer and the active ingredient. A covalent bond can be formed between the active ingredient and such attached linker group or the active ingredient can be covalently bonded to a linker group and the linker group/active ingredient attached to the polymer. Covalent bonds that can be cleaved under acidic conditions include bonds of the following types: silyl ethers and esters, acetals, thioacetals, imines, amins, carbonates, and vinyl ethers. A preferred covalent bond that can be cleaved within the preferred pH range is a silyl ether covalent bond. Silyl ether covalent bonds are especially preferred because such a bond can be formed between a silyl functional group on the polymer (or linker group) and an hydroxyl functional groups on the active ingredient (col.5, lines 40-57). A preferred polymer is a polymer selected from polyamine, polybutadiene, copolymers of 1,3-dienes and any polymer having a derivatizable olefinic bond. An especially preferred polymer is a polymer which is a functionalized polybutadiene containing amino functional groups. Such a polymer is preferred because the amino functional groups are capable of bonding with an active ingredient or a linker group. (col. 6, lines 9-20). The polymer may be crosslinked by crosslinking agents presented in col. 6, lines 42-47.

However, Tremont does not anticipate or suggest fairly that the covalent bond between the linker and polymer is a N-C or P-C covalent bond.

No other prior art that anticipates or suggests fairly the instant claims has been located as of the date of this Office Action. Therefore, claims 15-20 are allowed over the prior art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tatyana Zalukaeva whose telephone number is (571) 272-1115. The examiner can normally be reached on 9:00 - 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on (571) 272-1114. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

11/26/04

Tatyana Zalukaeva  
Primary Examiner  
Art Unit 1713

